

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of LI *et al.*

Group Art Unit: 1616

Application Serial No.: TBD

Examiner: Hartley, M.

Filed: July 14, 2003

Docket No.: 1401S

For: WATER SOLUBLE PACLITAXEL DERIVATIVES

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

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**Charge any fee due to our
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The attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached Form SB-08. The references have been submitted to the Examiner in the parent application and are not attached herewith. Additional copies of references are available on request. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 CFR 1.97(b)(1)(2)(3).
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance. 37 CFR 1.97(c)(1)(2).
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
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- ☐ c. Please debit or credit the \$240.00 fee to Account No. 03-1182 under 37 C.F.R. 1.17(p), or as needed to ensure consideration of the disclosed information. A duplicate copy of this paper is attached.
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Applicants respectfully request that the listed documents be considered by the Examiner and formally be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609. The references listed in the attached SB-08 have been submitted in the parent application. Additional copies are available on request.

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Respectfully submitted,

Date: July 14, 2003

By: 
Donald W. Wyatt, Reg. No. 40,879
Attorney for Applicants

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | |
| | | | | Filing Date July 14, 2003 | |
| Date Submitted: March 22, 2002 (use as many sheets as necessary) | | | | First Named Inventor LI | |
| | | | | Group Art Unit 1616 | |
| Sheet 1 of 11 | | | | Examiner Name Hartley | |
| | | | | Attorney Docket Number 1401S | |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
| | A1 | 2001/0034363 | A1 | Li et al. | 10/25/2001 | |
| | A2 | 2002/0016285 | A1 | Bhatt et al. | 02/07/2001 | |
| | A3 | 4,356,166 | | Peterson et al. | 10/26/1982 | |
| | A4 | 4,942,184 | | Haugwitz et al. | 07/17/1990 | |
| | A5 | 4,943,579 | | Vishnuvajjala et al. | 07/24/1990 | |
| | A6 | 4,960,790 | | Stella et al. | 10/02/1990 | |
| | A7 | 5,059,699 | | Kingston et al. | 10/22/1991 | |
| | A8 | 5,087,616 | | Myers et al. | 02/11/1992 | |
| | A9 | 5,169,933 | | Anderson et al. | 12/08/1992 | |
| | A10 | 5,219,564 | | Zalipsky et al. | 06/15/1993 | |
| | A11 | 5,340,817 | | Wall et al. | 08/23/1994 | |
| | A12 | 5,362,831 | | Mongelli | 11/08/1994 | |
| | A13 | 5,380,751 | | Chen et al. | 01/10/1995 | |
| | A14 | 5,422,364 | | Nicolaou et al. | 06/06/1995 | |
| | A15 | 5,468,769 | | Klein et al. | 11/21/1995 | |
| | A16 | 5,473,055 | | Mongelli et al. | 12/05/1995 | |
| | A17 | 5,489,525 | | Pastan | 02/06/1996 | |
| | A18 | 5,545,880 | | Bu et al. | 08/13/1996 | |
| | A19 | 5,569,720 | | Mongelli et al. | 10/29/1996 | |
| | A20 | 5,583,153 | | Brahn | 12/10/1996 | |
| | A21 | 5,607,859 | | Gustavson et al. | 03/04/1997 | |
| | A22 | 5,614,549 | | Greenwald et al. | 03/04/1997 | |
| | A23 | 5,621,001 | | Canetta et al. | 04/15/1997 | |
| | A24 | 5,626,862 | | Brem et al. | 05/06/1997 | |
| | A25 | 5,629,433 | | Zheng et al. | 05/13/1997 | |
| | A26 | 5,641,803 | | Carretta et al. | 06/24/1997 | |
| | A27 | 5,646,159 | | Wall et al. | 07/08/1997 | |
| | A28 | 5,648,506 | | Desai et al. | 07/15/1997 | |
| | A29 | 5,716,981 | | Hunter et al. | 02/10/1998 | |
| | A30 | 5,719,265 | | Mongelli et al. | 02/17/1998 | |
| | A31 | 5,730,968 | | Butterfield et al. | 03/24/1998 | |
| | A32 | 5,733,925 | | Kunz et al. | 03/31/1998 | |
| | A33 | 5,762,909 | | Uzgrlis | 06/09/1998 | |
| | A34 | 5,773,522 | | Angelucci et al. | 06/30/1998 | |
| | A35 | 5,776,925 | | Young et al. | 07/07/1998 | |
| | A36 | 5,783,178 | | Kabanov et al. | 07/21/1998 | |
| | A37 | 5,811,447 | | Kunz et al. | 09/22/1998 | |
| | A38 | 5,837,873 | | Tsujihara et al. | 11/17/1998 | |
| | A39 | 5,846,565 | | Brem et al. | 12/08/1998 | |
| | A40 | 5,854,006 | | Hanigan et al. | 12/29/1998 | |
| | A41 | 5,873,904 | | Ragheb et al. | 02/23/1999 | |
| | A42 | 5,880,131 | | Greenwald et al. | 03/09/1999 | |
| | A43 | 5,886,026 | | Hunter et al. | 03/23/1999 | |

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| Examiner Signature | | Date Considered | |
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| Sheet | 2 | of | 11 | Attorney Docket Number | 1401S |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|----------------------|-----------|----|------------------|------------|
| | U.S. Patent Document | | | | |
| | A44 | 5,892,043 | | Tsujiyama et al. | 04/06/1999 |
| | A45 | 5,916,896 | | Wall et al. | 06/29/1999 |
| | A46 | 5,977,163 | | Li et al. | 11/02/1999 |
| | A47 | 5,981,568 | | Kunz et al. | 11/09/1999 |
| | A48 | 6,005,020 | | Loomis | 12/21/1999 |
| | A49 | 6,011,042 | | Greenwald et al. | 01/04/2000 |
| | A50 | 6,028,164 | | Loomis | 02/22/2000 |
| | A51 | 6,127,355 | | Greenwald et al. | 10/03/2000 |
| | A52 | 6,218,367 | B1 | Jacob | 04/17/2001 |
| | A53 | 6,262,107 | B1 | Li et al. | 07/17/2001 |

| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|-----------------------|-------------------------|---------------------|--------------------------------------|--|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Office ³ | Number ⁴ | Kind Code ⁵ (If known) | | | | |
| | A54 | WO | 93/10121 | A1 | Hans (w/Abstract) | 05/27/1993 | | |
| | A55 | JP | 5286868 | A | Kiyoshi et al. (w/Abstract) | 11/02/1993 | | |
| | A56 | WO | 95/03036 | A1 | Hunter et al. | 02/02/1995 | | |
| | A57 | WO | 95/13053 | A1 | Straubinger et al. | 05/18/1995 | | |
| | A58 | EP | 0589281 | B1 | Gasteler (w/Abstract) ** | 03/13/1996 | | |
| | A59 | WO | 96/25176 | A1 | Kunz et al. | 08/22/1996 | | |
| | A60 | EP | 0558959 | B1 | Uedal et al. | 04/16/1997 | | |
| | A61 | WO | 97/33552 | A1 | Li et al. | 09/18/1997 | | |
| | A62 | WO | 99/17804 | A1 | Angelucci et al. | 04/15/1999 | | |
| | A63 | WO | 99/49901 | A1 | Li et al. | 10/07/1999 | | |
| | A64 | EP | 0604910 | B1 | Golik et al. | 06/14/2000 | | |
| | A65 | WO | 01/70275 | A2 | Bhatt et al. | 09/27/2001 | | |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ⁶ |
| | A66 | BALOG ET AL., "Total Synthesis of (-) Epothilone A," <i>Angew. Chem. Int. Ed. Engl.</i> , Vol. 35, 1996, pp. 2801-2803 © VCH Verlagsgesellschaft mbH, Weinheim | | |
| | A67 | BARTOLI ET AL., " <i>In Vitro</i> and <i>In Vivo</i> Antitumoral Activity of Free, and Encapsulated Taxol," <i>J. Microencapsulation</i> , Vol. 7, 1990, pp. 191-197 © Taylor & Francis Ltd. | | |
| | A68 | BOM ET AL., "The Novel Silatecan 7- <i>tert</i> -Butyldimethylsilyl-10-hydroxycamptothecin Displays High Lipophilicity, Improved Human Blood Stability, and Potent Anticancer Activity," <i>Journal of Medicinal Chemistry</i> , Vol. 43, No. 21, 2000, pp. 3970-3980, © American Chemical Society | | |
| | A69 | BORMAN, S., "Epothilone Epiphany: Total Syntheses," <i>C&EN</i> , Vol. 74, 1996, pp. 24-26 © American Chemical Society | | |

| | | | |
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| Examiner Signature | | Date Considered | |
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| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|--|----------------|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² | |
| | A70 | CAIOLFA ET AL., "Polymer-bound camptothecin: initial biodistribution and antitumor activity studies," <i>Journal of Controlled Release</i> , Vol. 65, 2000, pp. 105-119, © Elsevier Science B.V. | | |
| | A71 | CONOVER ET AL., "Camptothecin delivery systems: enhanced efficacy and tumor accumulation of camptothecin following its conjugation to polyethylene glycol via a glycine linker," <i>Cancer Chemother Pharmacol</i> , Vol. 42, 1998, pp. 407-414, © Springer-Verlag | | |
| | A72 | CONOVER ET AL., "Camptothecin Delivery Systems: The Utility of Amino Acid Spacers for the Conjugation of Camptothecin with Polyethylene Glycol to Create Prodrugs," <i>Anti-Cancer Drug Design</i> , Vol. 14, 1999, pp. 499-506, © Oxford University Press | | |
| | A73 | CONOVER ET AL., "Camptothecin Delivery Systems: The Antitumor Activity of a Camptothecin-20-0-Polyethylene Glycol Ester Transport Form," <i>Anticancer Research</i> , Vol. 17, 1997, pp. 3361-3368 | | |
| | A74 | CORTES ET AL., "Docetaxel," <i>J. of Clinical Oncology</i> , Vol. 13, 1995, pp. 2643-2655 © American Society of Clinical Oncology | | |
| | A75 | DE BONO ET AL., "Phase I Pharmacokinetic (PK) Study of Mag-CPT-(PNO 166148) A Polymer Derivative of Camptothecin (CPT)," <i>Pharmazie</i> | | |
| | A76 | DE VRIES ET AL., "Conjugation of Docetaxel (DTXL) to Poly L-Glutamic Acid (PG) Increases Anti-Tumor Efficacy," <i>Proceedings of the American Association for Cancer Research</i> , Vol. 41, 2000, pg. 323, Abstract No. 2051 | | |
| | A77 | DE VRIES ET AL., "CT-2103: A water soluble poly-L-glutamic acid (PG)-Paclitaxel (TXL) conjugate has enhanced efficacy on MDR-1+human colon carcinoma cell line xenografts compared to free TXL," <i>AACR</i> , 2001, Abstract No. 462 | | |
| | A78 | DE VRIES ET AL., "Optimization of the anti-tumor activity of water-soluble poly L-glutamic acid (PG)-paclitaxel (TXL) conjugates," <i>AACR-NCI-EORTC</i> 92, 1999, p. 22, Abstract No. 451, Washington, DC | | |
| | A79 | DE VRIES ET AL., "Pharmacokinetics (PK) and biodistribution of poly-(L)-glutamic acid (PG) paclitaxel (TXL) (CT-2103) in mice with subcutaneous B-16 melanomas," <i>Proceedings of the 11th AACR-NCI-EORTC Symposium</i> , 2000 Amsterdam, Netherlands | | |
| | A80 | DEUTSCH ET AL., "Synthesis of Congeners of Prodrugs. 3. Water-Soluble Prodrugs of Taxol with Potent Antitumor Activity," <i>J. Med. Chem.</i> , Vol. 32, 1989, pp. 788-792 © American Chemical Society | | |
| | A81 | DUNCAN ET AL., "Polymer-drug conjugates, PDEPT and PELT: basic principles for design and transfer from the Laboratory to Clinic," <i>Journal of Controlled Release</i> , Vol. 74, 2001, pp. 135-146, © Elsevier Science B.V. | | |
| | A82 | EISEMAN ET AL., "Plasma pharmacokinetics and tissue distribution of paclitaxel in CD2F1 mice," <i>Cancer Chemother. Pharmacol.</i> , Vol. 34, 1994, pp. 465-471 © Springer-Verlag | | |

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| Sheet | 4 | of | 11 | Attorney Docket Number | | 1401S | |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ⁵ |
| | A83 | FIDLER ET AL., "The Biology of Cancer Invasion and Metastasis," <i>Adv. Cancer Res.</i> , Vol. 28, 1978, pp. 149-250 © Academic Press, Inc. | | |
| | A84 | GILBERT ET AL., "Novel water soluble paclitaxel derivatives: Evaluation of PEG-paclitaxel's <i>in vitro</i> and <i>in vivo</i> effects," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 38, 1997, pg. 225, Abstract #1512 | | |
| | A85 | GOLDSPIEL, "Pharmaceutical Issues: Preparation, Administration, Stability, and Compatibility with Other Medications," <i>Ann. Pharmacotherapy</i> , Vol. 28, 1994, pp. S23-26, © Harvey Whitney Books Company | | |
| | A86 | GREENWALD ET AL., "Camptothecin-20-PEG Ester Transport Forms: the Effect of Spacer Groups on Antitumor Activity," <i>Bioorganic & Medicinal Chemistry</i> , Vol. 6, 1998, pp. 551-562, © Elsevier Science Ltd. | | |
| | A87 | GREENWALD ET AL., "Drug Delivery Systems. 2. Camptothecin 20- <i>O</i> -Poly(ethylene glycol) Ester Transport Forms," <i>J. Med. Chem.</i> , Vol. 39, 1996, pp. 1938-1940, © American Chemical Society | | |
| | A88 | GREENWALD ET AL., "Drug Delivery Systems: Water Soluble Taxol 2'-Poly(Ethylene Glycol) Ester Prodrugs-Design and <i>In Vivo</i> Effectiveness," <i>J. Med. Chem.</i> , Vol. 39, 1996, pp. 424-431 © American Chemical Society | | |
| | A89 | GREENWALD ET AL., "Highly Water Soluble Taxol Derivatives: 2'-Polyethylene Glycol Esters as Potential Products," <i>J. Org. Chem.</i> , Vol. 60, 1995, pp. 331-336 © American Chemical Society | | |
| | A90 | GREENWALD ET AL., "Highly Water Soluble Taxol Derivatives: 2'-polyethyleneglycol esters as potential prodrugs," <i>Bioorganic & Medicinal Chemistry Letters</i> , Vol. 4, 1994, pp. 2465-2470 © Elsevier Science Ltd. | | |
| | A91 | GREENWALD ET AL., "Stereoselective acylation of 20-(<i>S</i>)-camptothecin with amino acid derivatives using scandium triflate/DMAP," <i>Tetrahedron: Asymmetry</i> , Vol. 9, 1998, pp. 915-918, © Elsevier Science Ltd. | | |

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| Sheet | 5 | of | 11 | | |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|--|----------------|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² | |
| | A92 | GREENWALD, "Camptothecin-20-PEG Ester Transport Forms: the Effect of Spacer Groups on Antitumor Activity", <i>Bioorganic & Medicinal Chemistry</i> , Vol. 6, 1998, pp. 551-562 © Elsevier Science Ltd. | | |
| | A93 | HIRANO ET AL., "Polymeric derivatives of activated cyclophosphamide as drug delivery systems in antitumor therapy pharmacologically active polymers, 20," <i>Makromol. Chem.</i> , Vol. 180, 1979, pp. 1125-1130 © Hüthig & Wepf Verlag, Basel, Heidelberg | | |
| | A94 | HOES ET AL., "Optimization of macromolecular prodrugs of the antitumor antibiotic adriamycin," <i>J. Controlled Release</i> , Vol. 2, 1985, pp. 205-213 © Elsevier Science Publishers B.V. | | |
| | A95 | HÖFLE ET AL., "Epothilone A and B – novel 16-membered macrolides with cytotoxic activity: isolation, crystal structure, and conformation in solution," <i>Angew. Chem. Int. Ed. Engl.</i> , Vol. 35, 1996, pp. 1567-1569 © VCH Verlagsgesellschaft mbH | | |
| | A96 | HORWITZ ET AL., "Taxol, mechanisms of action and resistance," <i>J. Natl. Cancer Inst. Monographs</i> , Vol. 15, 1993, pp. 55-61 | | |
| | A97 | KATO ET AL., "Antitumor activity of 1-β-D-arabinofuranosylcytosine conjugated with polyglutamic acid and its derivative," <i>Cancer Res.</i> , Vol. 44, 1984, pp. 25-30 | | |
| | A98 | KE ET AL., "Elevated serum VEGF as a prognosis marker in combined radiation and PG-TXL (CT-2103) therapy in mice with murine ovarian OCa-1 tumor," <i>Proc Amer Assoc Cancer Res</i> , Vol. 42, 2001, Abstract No. 3873 | | |
| | A99 | KE ET AL., "Schedule-independent radiosensitization of a murine ovarian OCa-1 tumor by PG-TXL," <i>Proc Am Assoc Cancer Res</i> , Vol. 40, 1999, Abstract No. 4223 | | |
| | A100 | KE ET AL., "Potentiation of radioresponse by polymer-drug conjugates," <i>J. Control Release</i> , Vol. 74, 2001, pp. 237-242 © Elsevier Science B.V. | | |

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| | | | | Filing Date | July 14, 2003 |
| | | | | First Named Inventor | LI |
| | | | | Group Art Unit | 1616 |
| | | | | Examiner Name | Hartley |
| Date Submitted: March 22, 2002 | | | | | |
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| | A101 | KOPECEK, "The potential of water-soluble polymeric carriers in targeted and site-specific drug delivery," <i>J. Controlled Release</i> , Vol. 11, 1990, pp. 279-290 © Elsevier Science Publishers B.V. | | |
| | A102 | KOUSKOFF ET AL., "Organ-specific disease provoked by systemic autoimmunity," <i>Cell</i> , Vol. 87, 1996, pp. 811-822 © Cell Press | | |
| | A103 | KUANG ET AL., "Poly(benzyl-L-glutamate) microcapsules: Their diagnostic and therapeutic potential," <i>Pharm. Res.</i> , Vol. 10, 1993, pg. S-191, Abstract PDD 7066 © Plenum Press | | |
| | A104 | LI ET AL., "Complete Regression of Well-Established Tumors Using a Novel Water-Soluble Poly-(L-Glutamic Acid)-Paclitaxel Conjugate," <i>Cancer Research</i> , Vol. 58, 1998, pp. 2404-2409 | | |
| | A105 | LI ET AL., "Synthesis and evaluation of PEG-paclitaxel conjugate as a water-soluble paclitaxel prodrug," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 37, 1996, p. 376, Abstract No. 2569 | | |
| | A106 | LI ET AL., "Cytotoxic and antitumor activity of water-soluble paclitaxel prodrug," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 37, 1996, pp. 376-377, Abstract No. 2570 | | |
| | A107 | LI ET AL., "Formation and characterization of CDDP loaded poly(benzyl L-glutamate) and poly (dl-lactic acid) microcapsules for chemoembolization," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 35, 1994, p. 336, Abstract No. 2003 | | |
| | A108 | LI ET AL., "Synthesis, biodistribution and imaging properties of indium-111-DTPA-paclitaxel in mice bearing mammary tumors," <i>J. Nucl. Med.</i> , Vol. 38, 1997, pp. 1042-1047 | | |
| | A109 | LI ET AL., "Water-soluble polyglutamic acid paclitaxel conjugate (PGA-paclitaxel): antitumor regression in rats bearing 13762 mammary carcinoma," <i>American Association Pharmaceutical Scientists Meeting</i> , Vol. 13, 1996, p. S368 | | |

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| | A110 | LI ET AL., "Synthesis and evaluation of water-soluble polyethylene glycol-paclitaxel conjugate as a paclitaxel prodrug," <i>Anticancer Drugs</i> , Vol. 7, 1996, pp. 642-618 | | |
| | A111 | LI ET AL., "Complete regression of well-established tumors using a novel water-soluble poly(L-glutamic acid)-paclitaxel conjugate," <i>Cancer Res</i> , Vol. 58, 1998, pp. 2404-2409 | | |
| | A112 | LI ET AL., "Antitumor activity of Poly(L-glutamic acid)-Paclitaxel on syngeneic and xenografted tumors," <i>Proc Am Assoc Cancer Res</i> , Vol. 40, 1999, Abstract No. 1909 | | |
| | A113 | LI ET AL., "Enhancement of tumor radioresponse of a murine ovarian carcinoma by poly(L-glutamic acid)-paclitaxel conjugate," <i>Ninth International Symposium on Recent Advances in Drug Delivery Systems</i> , 1999, Salt Lake City, UT | | |
| | A114 | LI ET AL., "Antitumor activity of Poly(L-glutamic acid)-Paclitaxel on syngeneic and xenografted tumors," <i>Clin Cancer Res</i> , Vol. 5, 1999, pp. 891-897 | | |
| | A115 | LI ET AL., "Tumor irradiation enhances the tumor-specific distribution of poly(L-glutamic acid)-conjugated paclitaxel and its antitumor efficacy," <i>Clin Cancer Res</i> , Vol. 6, 2000, pp. 2829-2834 | | |
| | A116 | LI ET AL., "Biodistribution of paclitaxel and poly(L-glutamic acid)-paclitaxel conjugate in mice with ovarian OCa-1 tumor," <i>Cancer Chemother Pharmacol</i> , Vol. 46, 2000, pp. 416-422 © Springer-Verlag | | |
| | A117 | LI ET AL., "Potentiation of ovarian OCa-1 tumor radioresponse by poly (L-glutamic acid)-paclitaxel conjugate," <i>Int.J Radiat. Oncol. Biol. Phys.</i> , Vol. 48, 2000, pp. 1119-1126 © Elsevier Science Inc. | | |
| | A118 | MAEDA ET AL., "Tumortropic and lymphotropic principles of macromolecular drugs," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , Vol. 6, 1989, pp. 193-210 © CRC Press | | |

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| | | | | First Named Inventor | LI |
| | | | | Group Art Unit | 1616 |
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| | A119 | MAGRI ET AL., "Modified Taxols. 2. Oxidation Products of Taxol," <i>J. Org. Chem.</i> , Vol. 51, 1986, pp. 797-802 © American Chemical Society | |
| | A120 | MATHEW ET AL., "Synthesis and evaluation of some water-soluble prodrugs and derivatives of taxol with antitumor activity," <i>J. Med. Chem.</i> , Vol. 35, 1992, pp. 145-151 © American Chemical Society | |
| | A121 | MASON ET AL., "Poly (L-glutamic Acid)-paclitaxel dramatically enhances the anti-tumor efficacy of radiotherapy," <i>AACR - NCI - EORTC</i> , Vol. 397, 2001, Miami Beach, Florida | |
| | A122 | MULTANI ET AL., "Paclitaxel and water-soluble poly (L-glutamic acid)-paclitaxel, induce direct chromosomal Abnormalities and cell death in a murine metastatic melanoma cell line," <i>Anticancer Res.</i> , Vol. 17, 1997, pp. 4269-4274 | |
| | A123 | MORIMOTO ET AL., "Antitumor agent poly (amino acid) conjugates as a drug carrier in cancer chemotherapy," <i>J. Pharm. Dyn.</i> , Vol. 7, 1984, pp. 688-698 | |
| | A124 | MOSMANN, "Rapid colorimetric assay for cellular growth and survival: application to proliferation and cytotoxic assay," <i>J. Immunol. Methods</i> , Vol. 65, 1983, pp. 55-63 © Elsevier Science Publishers B.V. | |
| | A125 | OLIVER ET AL., "Suppression of collagen-induced arthritis using an angiogenesis inhibitor, AGM-1470, and a microtubule stabilizer, Taxol," <i>Cellular Immunology</i> , Vol. 157, 1994, pp. 291-299 © Academic Press, Inc. | |
| | A126 | PESENTI ET AL., "Synthesis and biological activity of water soluble polymer-bound taxol derivatives," <i>Proc. Amer. Assoc. Cancer Res.</i> , Vol. 36, 1995, p. 307, Abstract No. 1824. | |
| | A127 | PHILLIPS-HUGHES ET AL., "Restenosis: pathophysiology and preventive strategies," <i>JVIR</i> , Vol. 7, 1996, pp. 321-333 © SCVIR | |

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| | | | | First Named Inventor | LT |
| | | | | Group Art Unit | 1616 |
| | | | | Examiner Name | Hartley |
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| | A128 | PRATESI ET AL., "Poly-L-Aspartic Acid as a Carrier for Doxorubicin: A Comparative <i>In vivo</i> Study of Free and Polymer-Bound Drug," <i>Br. J. Cancer</i> , Vol. 52, 1985, pp. 841-848 © The Macmillan Press Ltd. | | |
| | A129 | REYNOLDS ET AL., "Polymers help guide cancer drugs to tumor targets- and keep them there," <i>J. Natl. Cancer Institute</i> , Vol. 87, 1995, pp. 1582-1584 | | |
| | A130 | ROSE ET AL., "Preclinical antitumor activity of water-soluble paclitaxel derivatives," <i>Cancer Chemother. Pharmacol.</i> , Vol. 39, 1997, pp. 486-492 © Springer Verlag | | |
| | A131 | SCUDIERO ET AL., "Evaluation of a soluble tetrazolium/formazan assay for cell growth and drug sensitivity in culture using human and other tumor cell lines," <i>Cancer Research</i> , Vol. 48, 1988, pp. 4827-4833 | | |
| | A132 | SERRUYS ET AL., "A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease," <i>N. Engl. J. Med.</i> , Vol. 331, 1994, pp. 489-495 © The Massachusetts Medical Society | | |
| | A133 | SHAFFER ET AL., " <i>In vivo</i> identification of monoglutamyl paclitaxel metabolite from poly-L-glutamic acid-paclitaxel (CT-2103) in tumor bearing mice," <i>Proceedings of the 49th ASMA Conference on Mass Spectrometry and Allied Topics</i> , A010970, 2001 | | |
| | A134 | SHARMA ET AL., "Novel taxol formulations: preparation and characterization of taxol-containing liposomes," <i>Pharm. Res.</i> , Vol. 11, 1994, pp. 889-896 © Plenum Publishing Corp. | | |
| | A135 | SHI, "Poly (L-glutamic acid)-paclitaxel and paclitaxel have different pharmacological properties," <i>Proc. Amer. Assoc. for Cancer Research</i> , Vol. 39, 1998, p. 189, Abstract No. 1294 | | |
| | A136 | SINGER ET AL., "Poly-L-Glutamic Acid Paclitaxel Conjugate (PG-TXL): A water-soluble biodegradable conjugate with decreased toxicity and enhanced efficacy," <i>4th International Symposium on Polymer Therapeutics</i> , 2000 | | |

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| | | | | First Named Inventor | J.T. |
| | | | | Group Art Unit | 1616 |
| | | | | Examiner Name | Hartley |
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| | A137 | SINGER ET AL., "Conjugation of Camptothecins to Poly-(L-Glutamic Acid)," <i>Annals of the New York Academy of Sciences</i> , Vol. 922, 2000, pp. 135-150, © The New York Academy of Sciences | | |
| | A138 | TODD ET AL., "Phase I and pharmacological Study of CT-2103, a poly (L-glutamic Acid)-paclitaxel conjugate," <i>Journal of Clinical Oncology</i> , Vol. 439, 2001. | | |
| | A139 | VAN HEESWIJK ET AL., "The Synthesis and Characterization of Polypeptide-Adriamycin Conjugates and Its Complexes with Adriamycin. Part 1, <i>Journal of Controlled Release</i> , Vol. 1, 1985, pp. 301-315 Elsevier Science Publishers B.V. | | |
| | A140 | VYAS ET AL., "Phosphate-activated prodrugs of paclitaxel," <i>Taxane Anticancer Agents</i> , Chapter 9, 1995, pp. 124-137 © American Chemical Society | | |
| | A141 | WADKINS ET AL., "Water Soluble 20(S)-Glycinate Esters of 10,11-Methylenedioxycamptothecins Are Highly Active Against Human Breast Cancer Xenografts" <i>Cancer Research</i> , Vol. 59, 1999, pp. 3424-3428 | | |
| | A142 | WALL ET AL., "Plant Antitumor Agents. 30. ^{18,9} Synthesis and Structure Activity of Novel Camptothecin Analogs," <i>Journal of Medicinal Chemistry</i> , Vol. 36, 1993, pp. 2689-2700, © American Chemical Society | | |
| | A143 | WANG ET AL., "Recent Advances in the Discovery and Development of Topoisomerase Inhibitors as Antitumor Agents," <i>Medicinal Research Reviews</i> , Vol. 17, 1997, pp. 367-425, © John Wiley & Sons, Inc. | | |
| | A144 | WEISS ET AL., "Hypersensitivity reactions from taxol," <i>J. Clin. Oncol.</i> , Vol. 8, 1990, pp. 1263-1268 © American Society of Clinical Oncology | | |
| | A145 | WEN ET AL., "Potentiation of Antitumor Activity of PG-TXL with Anti-EGFR Monoclonal Antibody C225 in MDA-MB-468 Human Breast Cancer Xenograft," <i>Proc Am Assoc Cancer Res</i> , Vol. 41, 2000, Abstract No. 2052 | | |

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| | A146 | YANG ET AL., "Application of surface-modified microcapsules to target estrogen receptors," <i>Pharm. Res.</i> , Vol. 9, 1992, p. S73, Abstract No. Biotec 2027 | | |
| | A147 | YANG ET AL., "Diagnostic and therapeutic potential of poly(benzyl L-glutamate)," <i>J. Pharm. Sci.</i> , Vol. 83, 1994, pp. 328-331 © American Chemical Society and American Pharmaceutical Association | | |
| | A148 | YU, "Effect of polymer structure on antitumor activity of polyaminio acid-paclitaxel conjugates," <i>Proc. Amer. Assoc. Cancer Research</i> , Vol. 39, 1998, p. 167, Abstract No. 1144 | | |
| | A149 | ZHANG ET AL., "An investigation of the antitumor activity and biodistribution of polymeric micellar paclitaxel," <i>Cancer Chemother. Pharmacol.</i> , Vol. 40, 1997, pp. 80-86 © Springer-Verlag | | |
| | A150 | ZHAO ET AL., "Modified taxols. 6. preparation of water-soluble taxol phosphates," <i>J. Nat. Prod.</i> , Vol. 54, 1991, pp. 1607-1611 | | |
| | A151 | ZHENG ET AL., "Deacetylation of Paclitaxel and Other Taxanes," <i>Tetrahedron Letters</i> , Vol. 36, 1995, pp. 2001-2004, © Elsevier Science Ltd. | | |
| | A152 | ZUNINO ET AL., "Anti-Tumor Activity of Daunorubicin Linked to Poly-L-Aspartic Acid," <i>Int. J. Cancer</i> , Vol. 30, 1982, pp. 465-470 | | |

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